

NOTE: This order is nonprecedential.

**United States Court of Appeals
for the Federal Circuit**

In Re ENTRESTO (SACUBITRIL/VALSARTAN)

NOVARTIS PHARMACEUTICALS CORPORATION,
Plaintiff-Appellee

v.

**MSN PHARMACEUTICALS, INC., MSN
LABORATORIES PRIVATE LTD., MSN LIFE
SCIENCES PRIVATE LTD.,**
Defendants-Appellants

2025-1722, 2025-1723

Appeals from the United States District Court for the
District of Delaware in Nos. 1:19-cv-02053-RGA and 1:20-
md-02930-RGA, Judge Richard G. Andrews.

ON MOTION

Before LOURIE, MAYER, and DYK, *Circuit Judges*.
DYK, *Circuit Judge*.

O R D E R

Appellants MSN Pharmaceuticals, Inc. et al. (collectively, “MSN”) move for a stay pending appeal and to expedite briefing. Novartis Pharmaceuticals Corporation opposes. MSN replies. Because MSN’s motion has failed to show a sufficient likelihood of success regarding its challenges to the district court’s decision denying relief from the final judgment, we deny the motion for a stay. We also deny the motion to expedite the appeals.

BACKGROUND

This is the second time this Hatch-Waxman case involving Novartis’s Entresto® drug is before us on appeal. As noted in the prior appeal, “Entresto includes valsartan and sacubitril in a specific form known as a ‘complex,’ which combines the two drugs into a single unit-dose-form through weak, non-covalent bonds.” *In re Entresto*, 125 F.4th 1090, 1093 (Fed. Cir. 2025). Entresto’s Orange Book listing includes Novartis’s U.S. Patent No. 8,101,659 (“the ’659 patent”), *id.*, which claims a “pharmaceutical composition comprising” sacubitril and valsartan wherein they are “administered in combination,” *id.* at 1094 (citing ’659 patent, col. 16 ll. 17–33). That patent has now expired, but Novartis was granted a period of pediatric exclusivity through July 15, 2025, in part due to its Orange Book listing of the ’659 patent.

Novartis brought this suit against MSN in the United States District Court for the District of Delaware asserting the ’659 patent after MSN had submitted an Abbreviated New Drug Application (“ANDA”) for a generic version of Entresto. During claim construction, MSN argued the claims required valsartan and sacubitril to be “two separate components” (“*i.e.*, in a non-complexed form”). *Id.* at 1095. The district court rejected that argument, construing the claims to merely have them “in combination.” *Id.* MSN later stipulated to infringement. Following a bench trial, the district court ruled that the asserted claims were not invalid for obviousness or lack of enablement but were

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invalid for lack of an adequate written description because complexes of these chemicals were unknown until after the priority date. *Id.* at 1097.

On appeal, this court reversed. MSN had not challenged claim construction and had stipulated to infringement of the as-construed claims. Thus, we focused on whether the patent adequately described what was claimed—a combination of valsartan and sacubitril—and concluded it had. *Id.* at 1098. We observed that the '659 patent does not specifically claim valsartan-sacubitril complexes, and that, in requiring further disclosure of such a complex, the district court had “erroneously conflated the distinct issues of patentability and infringement.” *Id.* Having rejected MSN’s invalidity challenges, we reversed and enjoined MSN from launching its generic product.

After this court denied rehearing and issued mandate, the district court entered judgment enjoining MSN from launching until July 16, 2025, and ordered that MSN’s ANDA approval reset to “no earlier” than that date pursuant to 35 U.S.C. § 271(e)(4)(A). ECF No. 5-2, Add127. MSN then sought relief from the judgment under Rules 59(e), 60(b)(5), and 60(b)(6) of the Federal Rules of Civil Procedure. Relying on our observation that the '659 patent does not specifically claim valsartan-sacubitril complexes, MSN argued that this court’s opinion had “significantly changed the scope of what the '659 patent claims” and, as such, it no longer infringes the patent and should be allowed to assert a counterclaim to delist it from the Orange Book.¹ ECF No. 5-2, Add136. The district court denied the motion and generally denied MSN’s motion to stay that decision.²

¹ See 21 U.S.C. § 355(j)(5)(C)(ii)(I).

² The district court temporarily stayed the § 271(e)(4)(A) aspect of its judgment at MSN’s request. This court then extended the district court’s stay pending consideration of the motion. See ECF No. 13.

MSN then filed these appeals and now asks this court for a stay pending appeal.

DISCUSSION

Rule 8(a)(2) of the Federal Rules of Appellate Procedure authorizes this court to stay a district court order pending appeal. Our determination is generally governed by four factors: (1) whether the movant has made a strong showing of a likelihood of success on the merits; (2) whether the movant will be irreparably injured absent a stay; (3) whether issuance of the stay will substantially injure the other parties interested in the proceeding; and (4) where the public interest lies. *Ohio v. Env't Prot. Agency*, 603 U.S. 279, 291 (2024) (citing *Nken v. Holder*, 556 U.S. 418, 434 (2009)). In reviewing a decision on a motion under Rules 59 and 60, we use the standard of review applicable in the regional circuit. *See Salix Pharms., Ltd. v. Norwich Pharms. Inc.*, 98 F.4th 1056, 1069 (Fed. Cir. 2024) (citation omitted). The United States Court of Appeals for the Third Circuit reviews a decision on such motions for an abuse of discretion. *See Lazaridis v. Wehmer*, 591 F.3d 666, 669 (3d Cir. 2010); *Budget Blinds, Inc. v. White*, 536 F.3d 244, 251 (3d Cir. 2008).

Rule 59(e) allows a district court to alter or amend a judgment to correct “manifest errors of law or fact or to present newly discovered evidence.” *Max’s Seafood Cafe ex rel. Lou-Ann, Inc. v. Quinteros*, 176 F.3d 669, 677 (3d Cir. 1999) (cleaned up). “The scope of a motion for reconsideration . . . is extremely limited.” *Blystone v. Horn*, 664 F.3d 397, 415 (3d Cir. 2011). “Such motions are not to be used as an opportunity to relitigate the case; rather, they may be used only to correct manifest errors of law or fact or to present newly discovered evidence.” *Id.* “A proper 59(e) motion therefore must rely on one of three grounds: (1) an intervening change in controlling law; (2) the availability of new evidence; or (3) the need to correct clear error of law or prevent manifest injustice.” *Lazaridis*, 591 F.3d at 669.

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Here, MSN failed to convince the district court that our decision constituted an intervening change in law or that altering the judgment was needed to correct a clear error of law or prevent manifest injustice. The district court noted that MSN had stipulated to infringement, MSN did not challenge the claim construction on appeal, and this court did not alter the claim construction on appeal. And while this court noted that the patent claims a combination of valsartan and sacubitril and not their specific complexes, the district court explained that does not change the scope of the patent in a way that would permit post-judgment relief.

Without prejudicing the merits panel's consideration following more fulsome briefing, we find that MSN has not shown in its motion papers that it is likely to succeed in demonstrating that the district court abused its discretion in declining to allow amendment of the complaint to state a delisting counterclaim.

MSN's motions papers likewise fail to show it is likely to succeed in overturning the district court's denial of its motion under Rule 60(b), which authorizes relief from a judgment if, as invoked here, "applying it prospectively is no longer equitable" or based on the existence of "extraordinary circumstances that justify reopening the judgment." Fed. R. Civ. P. 60(b)(5)–(6); *Budget Blinds*, 536 F.3d at 255 (interpreting Rule 60(b)(6)). MSN argues that, in light of this court's statement that the patent does not claim valsartan-sacubitril complexes, it is no longer equitable or appropriate to enforce Novartis's pediatric exclusivity period because the patent should not be listed in the Orange Book. But MSN could have sought to add a delisting counterclaim at some point in the prior five years of this litigation, yet it failed to do so. Under such circumstances, and again without prejudice to the merits panel's decision, we cannot say that MSN has shown sufficient likelihood of success on this challenge for a stay either.

Because we find, based on the papers submitted, that MSN has not made a sufficient showing of likelihood of success on appeal, we deny a stay pending appeal, and we lift the temporary stay previously ordered. MSN has also requested “a merits briefing schedule that would permit this Court to rule on the merits of this appeal prior to July 15, 2025.” ECF No. 16-1 at 19. However, MSN has not availed itself of the opportunity to self-expedite by filing its opening brief early and has not even proposed a briefing schedule. Under such circumstances, we decline to grant its request to expedite the briefing and argument schedule.

Accordingly,

IT IS ORDERED THAT:

- (1) The temporary stay imposed by this court’s May 2, 2025 order (ECF No. 13) is lifted.
- (2) MSN’s motion is denied.

FOR THE COURT



Jarrett B. Perlow
Clerk of Court

May 23, 2025
Date